DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0486]

Determination That PIPRACIL (Piperacillin Sodium) 2-Gram, 3-Gram, and 4-Gram Vials Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for piperacillin sodium 2-gram, 3-gram, and 4-gram vials.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical

testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials are the subject of approved NDA 50–545 held by Lederle (part of Wyeth-Ayerst Pharmaceuticals). PIPRACIL is a broad-spectrum penicillin indicated for the treatment of serious infections and for prophylactic use in surgery. The holder of the application for PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials has informed FDA that the drug products have been withdrawn from sale.

The agency has determined that Wyeth-Ayerst's PIPRACIL 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data

for possible postmarketing adverse event reports and has found no information that would indicate these products were withdrawn for reasons of safety or effectiveness.

For the reasons outlined, FDA determines that Wyeth-Ayerst's PIPRACIL 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials may be approved by the agency.

Dated: October 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S